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Provisions of CFDA Responsibilities and Departments

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Report Highlights:
In early March, 2013, the State Council announced the formation of the China National Food and Drug Administration (CFDA), a new ministerial-level agency created to increase vertical integration and focused oversight of food safety regulation. CFDA will assume responsibilities that were formerly divided among several ministries and administrations (MOH, AQSIQ, SAIC and SFDA). On March 26th, a Notice of the General Office of the State Council provided more detail on CFDA responsibilities and staffing.

This report provides an unofficial translation of the State Council notice.

General Information:

TRANSLATION BEGIN

Notice of the State Council Concerning Printing and Circulation of the "Provisions of CFDA Responsibilities, Departments and Staffing"

Guo Ban Fa [2013] No.24

Municipal governments in all provinces, autonomous regions and municipalities, ministries and commissions and organizations directly under the State Council,

The State Council has approved the "Provisions of CFDA Responsibilities, Departments and Staffing", which is ready for distribution.

General Office of the State Council
March 26, 2013

Provisions of Responsibilities, Departments and Staffing of the China Food and Drug Administration

Pursuant to the "State Council Plans for Government Institutional Reform and Function Change" and the "State Council Notice Concerning Government Institutional Framework" (Guo Fa [2013] No.14) approved in the First Session of the Twelfth National People's Congress, the State Council establishes the China Food and Drug Administration (CFDA, ministry level administration), which is an organization directly under supervision of the State Council.

I. Change of Responsibilities

1. Responsibilities to be abolished

   1) The administrative licensing for drug production and the administrative certification for good practices in drug production will be combined into one administrative licensing.

   2) The administrative licensing of drug distribution and the administrative licensing of good drug supply practice certification will be combined into one administrative licensing.

   3) The administrative licensing of cosmetics production and the administrative licensing of good drug hygiene will be combined into one administrative licensing.

   4) Supervision of licensed pharmacists' continuing education will be transferred to the China Licensed Pharmacist Association.

   5) Other responsibilities pursuant to the "State Council Plans for Government Institutional

Reform and Function Change" will be abolished.

2. Responsibilities that are given to lower-level authorities

    1) To provincial food and drug administration: responsibility for good manufacturing practice (GMP) certification of drugs and medical equipment;

    2) To provincial food and drug administration: responsibility for drug re-registration and licensing of supplemental application (for drugs) that do not change inherent quality;

    3) To provincial food and drug administration: administrative licensing for changes of domestic-made Class III medical devices that do not alter the product's inherent quality;

    4) To provincial food and drug administration: administrative licensing of entrusted drug manufacturing;

    5) To provincial food and drug administration: administrative licensing of non-special purpose cosmetics imports;

    6) Other responsibilities that shall be transferred to lower level government agencies pursuant to the "State Council Plans for Government Institutional Reform and Function Change."

3. Integrated Responsibilities

    1) The responsibility of developing pharmacopoeia is transferred from the former MOH to CFDA.

    2) The responsibility for setting conditions of food safety testing institute qualification recognition and the responsibility for developing testing practices is transferred from the former MOH to CFDA.

    3) The administrative licensing and compulsory testing of cosmetics is transferred from AQSIQ to CFDA.

    4) The compulsory certification of medical devices is transferred from AQSIQ to CFDA and integrated into the management of medical device registration.

    5) To form a unified food safety testing and detection technology regime, food safety testing and detection institutes that were affiliated to AQSIQ and the former SFDA will be combined, then regulatory and testing work will be separated and a corporate governance structure will be established.

4. Responsibilities to be reinforced

    1) Management practices will innovate so that (food and drug) producers and traders bear the primary responsibility, recognizing the role of market, public monitoring and industry self-discipline to establish an effective food and drug safety mechanism.

    2) Food safety regime construction and comprehensive coordination will be reinforced; the drug standard system and the good manufacturing practices improved; drug registration and relevant administrative licensing optimized; food and drug risk warning and supervision over local governments improved; a mechanism that prevents regional and food safety risks caused by system defects established.

    3) Integration of food and drug testing/detection capacities promoted; non-government-affiliated testing and detection services receive fair treatment, government procurement

of services (rather than establishing its own facilities) expanded, technology support systems and scientific administration over food and drugs improved.

4) Food and drug law/regulation enforcement standardized; administrative enforcement transition to criminal justice improved; pursuant to laws and regulations, punishment of criminal violations of food and drug safety strengthened.

II. Major Responsibilities

1. CFDA develops draft laws, regulations, policies and plans for supervision over food safety (including food additives and health foods; this applies to the rest of the Provisions), drugs (including Chinese medicine and minority drugs; this applies to the rest of the Provision), medical devices and cosmetics; encourages food manufacturers to take the primary responsibility, local municipal governments take overall responsibility; CFDA establishes a direct notification system for significant food and drug issues, with oversight over the system; CFDA focuses on preventing regional food and drug safety risks and risks caused by system defects.
2. CFDA formulates implementation measures for food-related administrative licensing and supervises implementation. It establishes food safety risk detection and prevention mechanisms; it develops an annual national food safety inspection and improvement plan and organizes implementations of such plan. CFDA establishes a unified food safety information publicity system, which discloses information regarding severe food safety issues. CFDA participates in developing food safety risk surveillance plans and food safety standard development; CFDA carries out food safety risk surveillance work based on the food safety risk surveillance plan.
3. CFDA develops, publishes and supervises implementation of drug and medical device standards (such as the pharmacopoeia), and categorization of drugs/medical devices. CFDA develops and supervises implementation of good manufacturing practice (GMP) in drugs and medical device research, production, trading and usage. CFDA is in charge of drug and medical device registration and registration inspection. It oversees the surveillance mechanism for adverse drug reactions and medical device adverse events, conducts surveillance and responds to such events. CFDA designs and improves the licensed pharmacists qualification system, supervises licensed pharmacists registration. It participates in the development of the national basic drugs catalogue and implementation. CFDA develops measures for supervision over cosmetics and oversees its implementation.
4. CFDA designs and implements inspection over food, drug, medical devices and cosmetics; CFDA also investigates severe law violations. It is in charge of recall and disposal of problematic products.
5. CFDA is in charge of the food and drug safety incident response system; it organizes and guides incident response actions, investigates and provides follow-up work; CFDA shall make sure investigation results are followed by rectification and/or punishment.
6. CFDA formulates science and technology development plans for food and drug safety; it improves the food and drug testing and detection system, the electronic supervision system and tracking system.
7. CFDA is in charge of publicity, education, international exchange and cooperation on food and

drug safety issues; it advances establishment of the social credit system.

8. CFDA guides local authorities' food and drug supervision work; it regulates enforcement and improves the link between administrative enforcement and criminal justice work.
9. CFDA conducts routine Food Safety Commission (under the State Council) work. It coordinates comprehensive food safety supervision work, and encourages coordinated action (by all relevant agencies). It supervises and advises provincial governments in food safety supervision work and assesses their performance.
10. It conducts other tasks assigned by the State Council and the Food Safety Commission.

II. Departments in CFDA

Based on responsibilities listed above, CFDA will set up 17 departments:

1. General Office

The General Office is in charge of the normal CFDA functions, including works related to documentation, correspondence, meetings, confidential affairs, records and inspection; it is also responsible for transparency operation, security, confidential treatment, written complaints and visits.

2. Department of Comprehensive Affairs (Policy Study Office)

The Department handles daily work of the (State Council) Food Safety Commission, as well as assesses food safety supervision work by other ministries/administrations and provincial governments. It analyzes and drafts key policies governing food, drug, medical devices and cosmetics.

3. Department of Legal Affairs

The Department organizes laws, regulations and rule drafting work; it is in charge of legal examinations and verification of regulatory documents; it also undertakes administrative enforcement supervision, administrative reconsideration and administrative lawsuits responses, etc.

4. Food Safety Supervision Department I

The Department oversees food safety in the production link; it identifies problems, and provides proposals for improving systems and practices; it advises lower level government agencies on administrative licensing and supervision work; the Department detects and improves activities that violate laws, regulations or which are inappropriate in a timely manner.

5. Food Safety Supervision Department II

The Department oversees food safety in the distribution and consumption link; it identifies problems, and gives proposals for improving systems and practices; it advises lower level government agencies on administrative licensing and supervision work; the Department detects and improves activities that violate laws, regulations or which are inappropriate in a timely manner.

6. Food Safety Supervision Department III

The Department is in charge of statistical work related to food safety; analyzing and forecasting the overall food safety situation; organizing food safety risk surveillance and risk communication; participating in the development of food safety risk surveillance plans, and conducting surveillance pursuant to the plans.

7. Department of Drug and Cosmetics Registration (Chinese Medicine and Minority Medicine

Supervision Department)

The Department handles drug registration and administrative licensing of some cosmetic products following strict conditions and procedures provided in laws and regulations. It shall improve procedures for registration and administrative licensing; supervise the practice of non-clinical studies and clinical studies of drugs, good manufacturing practice of prepared decoction pieces of herbal medicine, and implement the "Protection of Traditional Chinese Medicine Varieties" mechanism.

8. Department of Medical Device Registration

The Department handles registration of domestic-made Class III medical devices and imported medical device products following strict conditions and procedures provided in laws and regulations. It shall improve procedures for registration, adopt categorized administration and supervise good manufacturing practices (GMP) of medical devices.

9. Department of Drug and Cosmetics Supervision

The Department analyzes drug and cosmetics safety; it identifies problems, and gives proposals for improving systems and practices; it advises lower level government agencies in administrative licensing and supervision work; detects and rectifies activities that violate laws, regulations or are inappropriate in a timely manner. The Department also supervises radioactive drugs, narcotic drugs, medicinal toxic drugs, psychotropic substances and pharmaceutical precursor chemicals. It conducts surveillance over adverse drug reaction and re-evaluates the reactions.

10. Department of Medical Device Supervision

The Department analyzes medical device safety; it identifies problems, and gives proposals for improving systems and practices; it advises lower level government agencies in administrative licensing and supervision work; detects and rectifies activities that violate laws, regulations or are inappropriate in a timely manner. It organizes and conducts surveillance over adverse medical device events and re-evaluates such events.

11. Inspection Bureau

The Bureau investigates severe food and drug safety violation cases, guides and supervises inspections by local governments; regulates the administrative enforcement actions and pushes forward the connection of administrative enforcement and criminal justice. The Bureau supervises recall and disposal of problematic products; it also guides local governments in reviewing drug, medical device and health food advertisements.

12. Department of Emergency Response

The Department advances the establishment of a food and drug safety response system; it organizes the formulation of emergency response plans and conducts drills for incident response; the Department investigates severe food and drug safety incidents, and guides local governments in food safety incident response.

13. Department of Science, Technology and Standard

The Department implements key science and technology projects for food and drug supervision; it encourages the establishment of food and drug testing/detection systems, and the establishment of an e-tracking system. The Department develops conditions for qualification of food and drug testing/detection institutes. It develops drug, medical device, and cosmetics standards. The Department also develops catalogues of packaging materials and containers that contact drugs; it sets requirement

standards on the materials/products, and participates in food safety standard development.

14. Department of News and Publicity

The Department sets up a unified publicity system for food safety information; it undertakes popularization of food and drug sciences, news and information.

15. Department of Human Resources

The Department is in charge of human resource management, staffing, team building, and staff training. It designs and improves the licensed pharmacist qualification system; it supervises and guides licensed pharmacist registration.

16. Department of Planning and the Accounting

The Department drafts and implements the food and drug safety plans. It undertakes budget estimation and financial accounting work, state-owned asset management and internal auditing work for CFDA and its affiliated institutes.

17. Department of International Corporation (Hong Kong, Macau and Taiwan Affairs Office)

The Department undertakes international exchange and cooperation (including exchange and corporation with Hong Kong, Macau and Taiwan).

(In addition to the 17 Departments listed above, CFDA also has the following agencies)

Party Committee: responsible for Party and the Masses (non-Party members) work of CFDA and its affiliated institutes in Beijing.

Bureau for Retirees: in charge of work related to CFDA retirees; guides retiree work by CFDA affiliated institutes.

IV. Staffing

CFDA will have a staff of 345 (including 2 for the Party Committee and the Food Safety Commission, 2 staff for posts in need and 20 staff for retiree issues. Within the 345, there is 1 commissioner, 4 deputy commissioners, one deputy commissioner assigned as Deputy Commissioner of the National Health and Family Planning Commission for coordination between CFDA and NHFPC; 60 director generals and deputy director generals (including one director for food safety, one director for drug safety, one deputy secretary of the Party Committee, and two directors for the retiree Bureau), and 10 food and drug inspectors.

V. Other Issues

1. CFDA also has the title of the State Council Food and Safety Commission Office (one Administration, but two titles).
2. Division of Responsibilities with Ministry of Agriculture

MOA supervises and regulates quality and safety of agricultural products for food use in the production link before the products enter the wholesale, retail or processing establishments; MOA is responsible for the supervision of quality and the use of veterinary drugs, feed, feed additives and other agricultural inputs, including pesticides and fertilizers. When agricultural products for food use enter the wholesale/retail or processing establishments, they are food products and are subject to supervision of CFDA. MOA supervises and regulates quality and safety of livestock slaughtering and raw milk purchasing. MOA and CFDA will establish a food safety tracking mechanism, strengthen cooperation

and guarantee the smooth transfer of responsibility to form joint regulatory forces.

3. Division of responsibilities with the National Health and Family Planning Commission

1) The Commission is responsible for food safety risk assessment and food safety standard development.

The Commission will work together with CFDA and other Ministries/Administrations in developing and implementing food safety risk surveillance plans. CFDA shall propose food safety risk assessment to be done to the Commission in a timely manner. If the Commission detects potential food safety risks in risk surveillance or receives reports of risks, it shall conduct testing and risk assessment, and notify CFDA of the assessment results in a timely manner. If the assessment conclusion is "unsafe", CFDA shall take immediate measures. The Commission shall develop or revise food safety standards in a timely manner. The Commission will improve corporate governance of the National Food Safety Risk Assessment Center (CFSA), and improve its Executive Board mechanism.

2) CFDA and the Commission jointly run the Pharmacopoeia Commission of China, and develop the National Pharmacopoeia.

3) CFDA and the Commission jointly establish the Severe Adverse Drug Reaction Notification Mechanism and the Joint Response Mechanism.

4. Division of Responsibilities with AQSIQ

1) AQSIQ supervises and regulates production of food-related products, such as food packaging materials, containers and food processing tools, etc. AQSIQ shall inform CFDA of the detection of potential risks caused by food-related products in a timely manner; CFDA then can take measures in the food production link and the distribution/consumption links. CFDA shall notify AQSIQ of food safety problems caused by food-related products, and the latter shall take measures in the production of such products.

2) AQSIQ supervises and inspects the safety and quality of food imports and exports. All food and food-related product imports shall comply with Chinese national food safety standards. AQSIQ shall collect and analyze information on import/export food safety, and provide its analysis to CFDA in a timely manner. Upon the discovery of food safety incident outbreaks abroad that may impact China's domestic market or the detection of severe food safety problems in imported foods, AQSIQ shall immediately initiate a risk early warning and take control measures; at the same time, AQSIQ shall notify the CFDA so that the latter can take appropriate (preventative) measures.

5. Division of responsibilities with SAIC

CFDA reviews advertising content of medicine, medical devices and health food; SAIC supervises advertising of medicine, medical devices and health food. CFDA reviews advertisements for its approved drugs, medical devices and health foods; it shall notify SAIC of illegal advertisements and give suggestions for corrections; based on which, SAIC shall take measures pursuant to relevant laws/regulations. The two ministries shall establish and improve a coordination and cooperative mechanism.

6. Division of responsibilities with MOFCOM

1) MOFCOM develops plans and policies for drug circulation; CFDA supervises drug circulation, and implements plans and policies developed by MOFCOM.

2) MOFCOM develops plans and policies for catering services and alcohol products circulation; CFDA supervises the safety of foods in catering services and the safety of alcohol products.

3) Before issuing import licenses for pharmaceutical precursor chemicals, MOFCOM shall obtain CFDA's consent.

7. Division of responsibilities with the Ministry of Public Security

The Ministry of Public Security is in charge of supervision and instruction of the investigation part in terms of food and drug criminal violations. CFDA and MPS shall establish a joint mechanism between administrative enforcement and the criminal judicial process. Should CFDA discover food and drug law violations that are believed to be a criminal violation, it shall hand it over to public security authorities in a timely manner, so MPS can investigate the violation, make decision to initiate an investigation or not, pursuant to laws. CFDA shall provide assistance to MPS should it request CFDA for testing, authentication and affirmation.

8. CFDA affiliate institutions: responsibilities and staffing of CFDA affiliated institutions shall be provided in a separate notice.

VI. Supplementary Provisions

The Provisions shall be interpreted by the State Commission Office for Public Sector Reform; adjustment of the Provisions shall be undertaken by the Office pursuant to relevant procedures.

TRANSLATION END